Food and Drug Administration
Center for Food Safety and Applied Nutrition
Office of Special Nutritionals

ARMS#

12927

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MEDWATCH

THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

For VOLUNTARY rep
by health professionals of a
events and product prob

Individual Safety Report

3082702-5-00

CFSAN 83864 12927

Page ___ of ___

A. Patient information

1. Patient identifier [redacted] In confidence

2. Age at time of event: 51 or Date of birth:

3 Sex: ☑ female ☐ male

4. Weight: ___ lbs or 63.9 kgs

B. Adverse event or product problem

1. ☑ Adverse event and/or ☐ Product problem (e.g., defects/malfunctions)

2 Outcomes attributed to adverse event (check all that apply)

- ☐ death ___ (mo/day/yr)
- ☐ life-threatening
- ☑ hospitalization – initial or prolonged
- ☐ disability
- ☐ congenital anomaly
- ☐ required intervention to prevent permanent impairment/damage
- ☐ other ___

3. Date of event (mo/day/yr): 2/23/98

4. Date of this report (mo/day/yr): 5/15/98

5 Describe event or problem

Patient had started on "Ephedria" Herbal weight loss product about 1 week prior to admission. Pt experienced loss of consciousness & new seizure onset (no previous history of seizure activity)

6 Relevant tests/laboratory data, including dates

All WNL

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MEDWATCH CTU

7. Other relevant history, including preexisting medical conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc)

NKA, ~~no prior med~~ Depression

C. Suspect medication(s)

1. Name (give labeled strength & mfr/labeler, if known)

#1 "Ephedria"

#2

2. Dose, frequency & route used

#1 unknown

#2

3. Therapy dates (if unknown, give duration) from/to (or best estimate)

#1 ≈2/18 - 2/25

#2

4 Diagnosis for use (indication)

#1 weight loss

#2

5 Event abated after use stopped or dose reduced

#1 ☑ yes ☐ no ☐ doesn't apply

#2 ☐ yes ☐ no ☐ doesn't apply

6 Lot # (if known)

#1

#2 unknown

7. Exp. date (if known)

#1

#2

8 Event reappeared after reintroduction

#1 ☐ yes ☐ no ☑ doesn't apply

#2 ☐ yes ☐ no ☐ doesn't apply

9. NDC # (for product problems only)

– –

10 Concomitant medical products and therapy dates (exclude treatment of event)

Paxil

D. Suspect medical device

1. Brand name

2 Type of device

3 Manufacturer name & address

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4. Operator of device

- ☐ health professional
- ☐ lay user/patient
- ☐ other

5. Expiration date (mo/day/yr)

6.

model # ___

catalog # ___

serial # ___

lot # ___

other # ___

7. If implanted, give date (mo/day/yr)

8. If explanted, give date (mo/day/yr)

9. Device available for evaluation? (Do not send to FDA)

☐ yes ☐ no ☐ returned to manufacturer on ___ (mo/day/yr)

10. Concomitant medical products and therapy dates (exclude treatment of event)

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E. Reporter (see confidentiality section on back)

[redacted]

2. Health professional? ☑ yes ☐ no

3. Occupation: Pharmacist

4. Also reported to

- ☐ manufacturer
- ☐ user facility
- ☐ distributor

5. If you do NOT want your identity disclosed to the manufacturer, place an " X " in this box. ☐

FDA

Mail to: MEDWATCH 5600 Fishers Lane Rockville, MD 20852-9787

or FAX to: 1-800-FDA-0178

FDA Form 3500 (6/93)

Submission of a report does not constitute an admission that medical personnel or the product caused or contributed to the event.

ADVICE ABOUT VOLUNTARY REPORTING

Report experiences with:

- medications (drugs or biologics)
- medical devices (including in-vitro diagnostics)
- special nutritional products (dietary supplements, medical foods, infant formulas)
- other products regulated by FDA

Report SERIOUS adverse events. An event is serious when the patient outcome is:

- death
- life-threatening (real risk of dying)
- hospitalization (initial or prolonged)
- disability (significant, persistent or permanent)
- congenital anomaly
- required intervention to prevent permanent impairment or damage

Report even if:

- you're not certain the product caused the event
- you don't have all the details

Report product problems – quality, performance or safety concerns such as:

- suspected contamination
- questionable stability
- defective components
- poor packaging or labeling

How to report:

- just fill in the sections that apply to your report
- use section C for all products except medical devices
- attach additional blank pages if needed
- use a separate form for each patient
- report either to FDA or the manufacturer (or both)

Important numbers:

- 1-800-FDA-0178 to FAX report
- 1-800-FDA-7737 to report by modem
- 1-800-FDA-1088 for more information or to report quality problems
- 1-800-822-7967 for a VAERS form for vaccines

If your report involves a serious adverse event with a device and it occurred in a facility outside a doctor's office, that facility may be legally required to report to FDA and/or the manufacturer. Please notify the person in that facility who would handle such reporting.

Confidentiality: The patient's identity is held in strict confidence by FDA and protected to the fullest extent of the law. The reporter's identity may be shared with the manufacturer unless requested otherwise. However, FDA will not disclose the reporter's identity in response to a request from the public, pursuant to the Freedom of Information Act.

FDA Form 3500-back **Please Use Address Provided Below – Just Fold In Thirds, Tape and Mail**

Department of Health and Human Services
Public Health Service
Food and Drug Administration
Rockville, MD 20857

Official Business
Penalty for Private Use $300

NO POSTAGE NECESSARY IF MAILED IN THE UNITED STATES OR APO/FPO

BUSINESS REPLY MAIL
FIRST CLASS MAIL PERMIT NO. 946 ROCKVILLE, MD

POSTAGE WILL BE PAID BY FOOD AND DRUG ADMINISTRATION

MEDWATCH
The FDA Medical Products Reporting Program
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20852-9787

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CLINICAL RESEARCH
& REVIEW/OSN HFS-452

DEPARTMENT OF HEALTH AND HUMAN SERVICE

Public Health Service

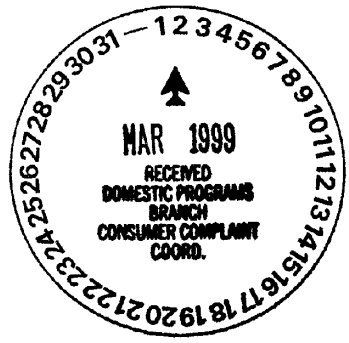
Food and Drug Administration
Detroit District Office
Central Region
1560 East Jefferson Avenue
Detroit, MI 48207-3179
Telephone: (313) 226-6260
FAX: (313) 226-3076

To: [redacted] Wallace/ ARMS Monitor, CFSAN/ HFS-636
Through Dennis R. Downer, SCSO, [redacted] DET-DO

From: George G. Calafactor, CSO, [redacted] DET-DO

Subj.: Adverse Event Project # 12927

Date: February 16, 1999



On 1/29/99, [redacted] received via fax from DET-DO, the 8/6/98 CFSAN request for follow –up on Adverse Event Report # 12927 (Ephedria herbal weight loss product). The assignment asks to follow-up on MEDWATCH complaint # 83864. – [redacted] is the MEDWATCH reporter.

This assignment had been inadvertently lost in DET-DO.

From 2/1-4/99, I attempted to contact Ms [redacted] via telephone @ [redacted] On 2/4/99,I finally reached Ms [redacted] I explained to her the assignment, apologizing about the follow-up delay. Since the complaint was about 1 year old, she would have to check the hospital records. However, per hospital policy, she explained that she was not allowed to supply me with the name/ address/ telephone # of the complainant until she has permission from the complainant. I informed her to contact the complainant then follow-up with me.

Since I have not heard back from Ms [redacted] I re-telephoned her on 2/10/99. She stated that she tried to reach the complainant; however, her telephone number had been disconnected. She assumes that the complainant had moved from the [redacted] area. She has no forwarding address/ telephone number for the complainant.

Since Ms [redacted] was not able to contact the complainant, the CFSAN assignment could not be completed.

George G. Calafactor, CSO
[redacted]
Detroit District

cc: DET-DO COMPLAINT FILES
[redacted] COMPLAINT FILES